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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/283,645	04/01/1999	VIKRAM KHETANI	CELG-0119	1269

7590

01/22/2004

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EXAMINER

CHANG, CELIA C

ART UNIT PAPER NUMBER

1625

DATE MAILED: 01/22/2004

25

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Appli cation No.

09/283,645

Applicant(s)

KHETANI ET AL.

Examiner

Celia Chang

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-- The MAILING DATE of this communication appears on the cov r sheet with the correspondenc address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 29 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 2-8, 10-13 and 15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 2-8, 10-13 and 15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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**DETAILED ACTION**

1. This application is a RCE of S.N. 08/283,645. Claims 2-8, 10-13, 15 are pending.

Claims 2-8, 10-13 and 15 are identical to the parent application except the dependency of claims 2-8, 10-13 are now made to be on claim 15.

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

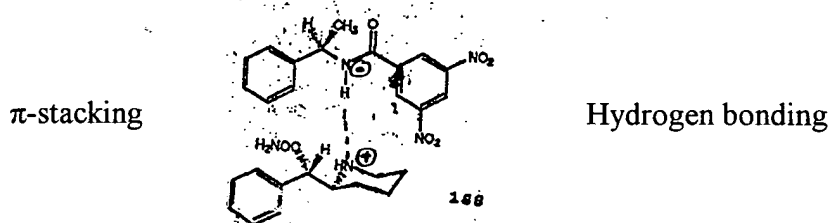
Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by Jursic et al.

Jursic et al. disclosed process of the claims, i.e. the exact compound in the enantiomeric forms, the acidic resolving agents (see p.1712-1713 structure and acidic functionality), and the salt complex (see p.1713 the complex of the acidic resolving agent and the amide compound is the formation of hydrogen bonding, Acidic---H---N---base, i.e. an amine salt).

The gist of applicants' argument is that

(1) Jursic should not be considered as an "acid resolving agent" because an acid requires "removable" hydrogen. Please note that it is well known that acid is "proton donor" or an "electron pair acceptor" (see Morrison and Boyd textbook supplied p.33), therefore, does not limit to "removable" hydrogen.

(2) Jursic did not disclosed the formation of a salt. In the instant case, a complex involving hydrogen bonding is formed between the amide moiety and the amine of the piperidine ring (claimed compound) to form a salt complex i.e.



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Such complexes are disclosed in table 1, page 1714, being formed between the resolving agents and enantiomers through amide hydrogen bonding for which delineation supra is made.

(3) Jursic does not disclosed isolation of salt. Please note that the complex formed between an acid and a base is a salt (see Morrison and Boyd textbook supplied p.34). The salts not only have been described but also isolated as seen in the chromatogram of p.1714. As described on p.1714 each peak of salt complex is identified, separated, and the chiral separating agent is recovered. Therefore, the rejection is proper when the scope of the claims are read with conventional well known definition for the terms and anticipation is found.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-8, 10-11, 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jursic et al. in view of Berrang et al. CA 97; Ohashi et al. CA 104; or Vanderplas et al. CA 118.

Jursic et al. disclosed process of separating enantiomeric isomers of the claims by formation of the racemic compounds with a chiral resolving agent (see p 1712-1713) in an organic solvent (see p 1713). The difference between the claims and Jursic et al. is that instead of the chiral resolving agents disclosed on p.1712, applicants used an alternative conventional chiral resolving agent. The well recognition of the claimed chiral resolving agents are found in Berrang et al., Ohashi et al. or Vanderplas et al. wherein enantiomeric amino compounds are resolved into stereo isomeric forms through formation of a stereo specific complex between the compounds and the chiral agent. One having ordinary skill in the art would be motivated to employ these conventional chiral resolving agents for separation of enantiomers knowing that such isomers have been separated with alternative chiral agents as disclosed by Jursic.

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Further, in so employing the conventional chiral resolving agents of the claims, a salt complex between the compound and the chiral agent, i.e. product of claim 13, is expected to form since it was taught by Jursic that such amine salt complex formation is through hydrogen bonding (p.1714).

Applicants argued that the difference of amide containing resolving agent of Jursic et al. would not motivate one skilled in the art to choose an alternative "acid" resolving agent. This is not persuasive because not only Jursic explicitly taught that the amides are acidic in function but also it is well recognized in the art that choosing an optical resolving agent is in its recognition of optical property. The well recognized tartaric acid as claimed is analogous to its amide i.e. the tartranilic acid (see US4,410,700 col.9, lines 41-42 and structural delineation of tartranilic acid) being acidic optical resolving agent. Therefore, artisan having ordinary skill in the optical resolution field would find that operability of the resolving agent disclosed by Jursic would motivate the picking and choosing of alternative resolving agent with expectation of reasonable success in separation of enantiomers.

4. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jursic et al. In view of Berrang et al. CA 97; Ohashi et al. CA 104; or Vanderplas et al. CA 118 further in view of Patrick et al.

The finding of prima facie obviousness over Jursic in view of Berrang, Ohashi or Vanderplas as delineated supra is also applicable here and incorporated here by reference. The instant claim 12 differs from the Jursic process in that an additional step for making the compounds from a pyridinyl precursor was incorporated. This precursor addition is also a conventional step in preparation of the claimed compounds as disclosed by Patrick (see p.487). Therefore, one having ordinary skill in the art who is well aware of all the pertinent art in the field, would be motivated to start the preparation from an alternative readily available precursor material as taught by Patrick with reasonable expectation of success.

5. Claims 1-8, 10-13 and 15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No.

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5,936,091. Although the conflicting claims are not identical, they are not patentably distinct from each other because the generic claims of the instant application included the patented claims and no acceptable terminal disclaimer has been filed.

6. This is a RCE of applicant's earlier Application No. 09/283,645 and all the claims are drawn to the same invention claimed in the earlier application which has been rejected and the rejection were all affirmed by the Board of Appeals and Interferences thus could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 703-308-4702. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner can be reached by facsimile at (703) 308-7922 with courtesy voice message supra.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

OACS/Chang  
Jan. 14, 2004

  
Celia Chang  
Primary Examiner  
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